IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. BAYER CORPORATION Defendant.	Case No. 2:07-cv-00001 (Hon. Jose L. Linares) (Hon. Joseph. A. Dickson) *Document Filed Electronically*

DEFENDANT'S REPLY BRIEF SHOWING CAUSE WHY IT SHOULD NOT BE HELD IN CIVIL CONTEMPT

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INTRODUCTION

The indefensible premise of the government's contempt motion is that Bayer must possess:

> "human clinical trials that (1) are randomized, placebo-controlled, and double-blind; (2) use the specific product for which the claims are made; (3) are performed in the population at which the claims are directed; and (4) use validated methods and appropriate statistical methods to assess "outcomes." Dkt No. 4-1 at 16.

The trials the government is demanding are *drug*-level randomized clinical trials ("Drug-Level RCTs"). Dkt. No. 84 at 6-7 (government brief distinguishing drug standard only by *number* of trials, not type of trial); 2nd Laine Dec. at 9, 15; Laine Tr. 56:7-12; Laine Tr. 229:14-21.[1] It is undisputed that *no one* in the industry, including Bayer, possesses a Drug-Level RCT. Thus, the only question is whether the government's new test is valid and enforceable.

As the Chamber of Commerce, the Council for Responsible Nutrition, and the Natural Products Association have all explained, the government's novel test is inconsistent with the governing statute, agency guidance, the terms of the consent decree, the First Amendment, and over twenty years of industry and agency practice. Dkt. Nos. 22; 24; 84; 89. Moreover, "[e]xperts in the field" do not "demand" Drug-Level RCTs. Dkt. No. 38 at 3, 7. Gastroenterologists do not require them, *see*

[1] "2nd Laine Dec," refers to Dr. Loren Laine's second declaration in this case, Dkt. No. 81-1. "Laine Tr." refers to the deposition transcript of Dr. Loren Laine filed with this Court with Bayer's opening brief, Dkt. No. 73-1 Exhibit A.

Fennerty Dec. at 3, and neither do primary-care physicians, microbiologists, geneticists, and nutrition scientists, *see* Merenstein Dec. at 14-16; Benson Dec. at 23; Blumberg Dec. at 7.[2] The only person who requires Drug-Level RCTs for dietary supplements is Dr. Laine, and only when he is conducting clinical trials, not when practicing gastroenterology. *See, e.g.*, Laine Tr. 153:11-16.[3]

In any event, even if the government's test were valid, it cannot be the basis for a contempt action. To prove contempt, the government must show, with "clear and convincing" evidence, a violation of a "clear and unambiguous" provision of the consent decree. *Harris v. City of Phila.*, 47 F.3d 1342, 1348, 1350 (3d Cir. 1995). The government has not done so, and cannot do so, with a novel test that was unveiled for the first time in the contempt motion—a test which no one in the industry meets.

Because the government's contempt motion is fatally flawed, the government shifts gears in its *fifth* brief. For the first time in this litigation, the government now claims that this case "is about answering one question: what evidence did Bayer possess and rely upon to substantiate the specific claims it has made for PCH since

[2] These citations refer to the first reports filed by Bayer's experts with Bayer's opening brief showing cause why it should not be held in contempt, Dkt. No. 73-1 Ex. B-E.

[3] In its final brief, the government presented a second purported expert, Dr. Frederic Bushman, but his declaration makes no mention of clinical trials. In his deposition, he said he would require Drug-Level RCTs, but he admitted he had no expertise and had never designed a single clinical trial of any kind. Bushman Tr. 71:2-21; 79:1-19 (Duffy Reply Cert. Exhibit E).

2008?" Dkt. No. 81 at 1. But this is not the only question in the case; indeed, it is not even *a* question in this case.

Attached to the government's brief is an internal Bayer memorandum that summarizes the comprehensive "literature review" Bayer conducted two years before the launch of PCH. Dkt. No. 81 Tab C Exh. 7 at 3. This review returned an "abundant number of matches" supporting PCH, including over a dozen human studies and two dozen textbooks from 2000 through 2006 alone. *Id.* at 3-9. Bayer produced these studies to the FTC. Bayer also explained that its scientists "regularly" reviewed the public literature on probiotics both before and after the product launch, and produced several dozen more public studies. Bayer's Response to Interrogatory No. 2 (Duffy Reply Cert Ex. J). Outside experts have confirmed that the public literature substantiates Bayer's claims. Fennerty Supp. Dec. at 2-3 (Duffy Reply Cert. Ex. A); Merenstein Supp. Dec. at 4-6 (Duffy Reply Cert. Ex. B).

Throughout the FTC's investigation, there was no question Bayer possessed and relied on volumes of public studies. Bayer produced almost 100 studies to the government. The government's eleventh-hour suggestion that Bayer had no substantiation for PCH is completely without support.

Equally unavailing is the government's criticism of the "post-hoc declarations from experts [Bayer] hired only recently." Dkt. No. 81 at 1. Bayer hired these experts "only recently" because the government introduced its novel test "only recently." The experts debunked the government's test as soon as the government unveiled it.

ARGUMENT

I. THE GOVERNMENT'S NOVEL TEST IS INVALID.

The Federal Trade Commission ("FTC") has failed—yet again—to meet one of the basic expectations in government: "the expectation of reasonableness." *Basic Research v. FTC*, No. 2:09-cv-0779, at 26-27 (D. Utah Nov. 25, 2014); *see also FTC v. Garden of Life*, 845 F. Supp. 2d 1328, 1335 (S.D. Fla. 2012) (rejecting attempts "to read additional requirements into the Consent Decree"), *aff'd in part and vacated in part*, 516 F. App'x. 852 (11th Cir. 2013). The agency is trying to impose "a level of substantiation that exceeds the requirements of the [consent decree]." *Basic Research*, at 27. This Court should follow its sister courts and reject the government's attempt.

A. The Consent Decree Does Not Require RCTs, Let Alone Drug-Level RCTs.

As the government admitted, the substantiation standard in Bayer's consent decree is identical to the standard that applies to the entire industry in the agency guidance. Government's Response to Requests for Admissions No. 1 (Dkt. No.73-1 Ex. G) (other than a typo). That standard requires only "competent and reliable scientific evidence." *Other* consent decrees that the FTC has entered into with *other* companies for *other* types of products require RCTs (though not Drug-Level RCTs). *See e.g., FTC v. Iovate Health Sci.*, Consent Decree at 7, No. 10-cv-587 (W.D.N.Y. 2010). But Bayer's decree does not.

The government contends that "the Guidance's flexibility allows for finding" a Drug-Level RCT requirement. Dkt. No. 81 at 7. But no court has ever made that "finding," and the Guidance itself makes no mention of Drug-Level RCTs or any RCTs.[4] The government previously sought this finding, but failed. *See Basic Research*, No. 2:09-cv-0779 at 26-27; *cf. Garden of Life*, 845 F. Supp. 2d at 1335 (rejecting attempt to misconstrue consent decree); *POM Wonderful v. FTC*, 777 F.3d 479, 479 (D.C. Cir. 2015) ("But unlike Part I [that has an RCT requirement], which applies . . . solely to disease-related claims, Part III contains no requirement that randomized, controlled, human clinical trials support more general claims about health benefits."); *id.* at 501 ("Part III's baseline requirement for all health claims does not require RCT[s].").

B. Experts In The Field Do Not Require Drug-Level RCTs.

Even if the "competent and reliable scientific evidence" standard "allowed for finding" a Drug-Level RCT requirement, there is no basis to make that novel finding in this case. In its contempt motion, the government's *only* basis for requiring Drug-Level RCTs was that "gastroenterologists," the "experts in the field," supposedly "demand[ed]" them. Dkt. No. 38 at 3; *see also* Dkt. No. 4-1 at 16 (asserting that relevant experts are "gastroenterolog[ists]," because the "specific discomforts" at issue "are digestive symptoms."). For five months, the government reasserted this position.

[4] The Guidance refers only to "clinical trials," which, as the government recognizes, are merely "test[s] done in humans." Government's Request for Interrogatories at 6 (Duffy Cert. Ex. I). There is no dispute that Bayer has human studies on PCH, but not Drug-Level RCTs.

See, e.g., Dkt. No. 38 at 10; Government's Response to Interrogatories Nos. 1-4 (Dkt. No. 73-1 Ex. H) (repeatedly relying on "Loren Laine, an eminent professional in *the relevant area (gastroenterology)*") (emphasis added).

But discovery proved this position to be baseless. Dr. Laine himself admitted that he does not demand RCTs of any kind when practicing gastroenterology, even when prescribing drugs with serious side effects. *See* Laine Tr. 153:11-16. His colleague, Dr. Fennerty, agreed that gastroenterologists do not require RCTs when practicing medicine or otherwise assessing the "efficacy of dietary supplements, including probiotics."[5] *See* Fennerty Dec. at 3. Gastroenterologists are not alone. Primary care physicians, microbiologists, geneticists, and nutrition scientists also do not require Drug-Level RCTs. Dkt. No. 74 at 22-32 (citing expert declarations).

Unable to defend its original theory, the government switched positions after discovery. The government no longer asks the Court to look to what gastroenterologists demand. In fact, the government now argues that the "practice of medicine" is "irrelevant." Dkt. No. 81 at 9-12.

[5] The government badly misrepresents the declarations from Dr. Fennerty and Dr. Merenstein when it asserts that they only spoke about evidence needed by physicians in clinical practice. Dkt. No. 81 at 21, 23. Both doctors made clear that there was competent and reliable scientific evidence that PCH was effective for its advertised claims. Fennerty Dec. at 4 ("Bayer's claims that PCH helps with constipation, diarrhea, gas and bloating is accurate and supported by competent and reliable scientific evidence."); Merenstein Dec. at 15 ("I have reviewed the scientific literature supporting Bayer's claims. . . these claims are valid and well-supported by competent and reliable scientific evidence."). In any event, as both doctors make clear in their supplemental declarations, the government is drawing a false distinction.

Instead, the government now relies on what undefined "*relevant experts* deem [] necessary under the 2007 Order to substantiate Bayer's advertising claims." Dkt. No 81 at 10 (emphasis added); *id.* at 11 (""what experts in the relevant area of study would generally consider to be adequate""). But this standard is impermissibly vague—who are the "relevant experts"?—and stunningly circular: The evidence Bayer needs is whatever "relevant experts deem [] necessary."

The government never expressly says so, but it appears to be embracing Dr. Laine's new view that the relevant experts are *clinical researchers*. *See* Dkt. No. 81 at 11 (quoting Dr. Laine and stating that ""the FTC gives great weight to accepted norms in the relevant fields of *research*"") (emphasis in original). In his deposition, Dr. Laine asserted that, although gastroenterologists do not demand RCTs, "clinical researchers" do when conducting research on *any* intervention—drugs, supplements, education brochures—in *any* area of medicine—rheumatology, ophthalmology, physical therapy, and also gastroenterology. Laine Tr. 56:7-12; Laine Tr. 229:14-21. If this is the government's new justification for its novel test, it fails for four reasons.

First, it was not presented in the government's contempt motion. The contempt motion claimed that gastroenterologists are the relevant experts, not clinical researchers. Dkt. No. 4-1 at 16 (asserting that "gastroenterology is the directly relevant area of expertise"). The government should not be allowed to change its position this late in the day—after eight briefs have been written, five experts have been deposed, and virtually all discovery has been completed.

Second, there is no basis for allowing clinical researchers to be the sole source of the determinative legal standard. *See* Dkt. No. 73-1 Ex. G at. No. 4-6 (agreeing that primary care physicians, microbiologists, and geneticists can be relevant experts). The case cited by the government, *In re Thompson Med. Co.*, 104 F.T.C. 648, 751 (1984), is inapposite. *Thompson* did not address the "competent and reliable scientific evidence" standard. In fact, it did not address dietary supplements at all; it addressed *drugs*. This distinction underscores the whole problem with the government's position in this case. As *amici* and Bayer explained, the government is attempting to treat dietary supplements like drugs, which is contrary to the governing statute, FTC Guidance, the terms of the consent decree, and over 20 years of industry practice.

Third, it is simply wrong to say that clinical researchers consider only Drug-Level RCTs in assessing "efficacy." As Dr. Fennerty, a gastroenterology clinician *and researcher* with over 300 papers to his name testified: "[E]ven from the narrow lens of a clinical researcher, level 1 RCTs are not required." Fennerty Dec. at 11. More specifically, *probiotic researchers* do not require Drug-Level RCTs. But Dr. Laine would not know that. As he admitted, he is not a probiotics expert, and has never done any research of any kind on any probiotics. *See* Laine Tr. 299:21-22 ("I am not an expert in probiotics, nor did I claim to be."); Laine Tr. 381:6-22; Laine Tr. 271:2-273:14. The government has not come forward with evidence that "clinical researchers" generally require Drug-Level RCTs for probiotic supplements, and the weight of the evidence is to the contrary. *See* Fennerty Dec. at 11; Merenstein Dec. at 3-6.

Fourth, as *amici* have explained, the Laine view would destroy the dietary supplement industry. *See, e.g.,* Dkt. No. 84 at 18-21. Dr. Laine made clear, in both his deposition and his most recent declaration, that he believes that Drug-Level RCTs are required for ***all*** interventions in ***all*** areas of research. *See* Dkt No. 81-1 at 9, 15 (Drug-Level RCTs are the "appropriate method to yield accurate and reliable results for efficacy of a product, even for supplements."); *see also id.* at 9 ("illogical scientifically" to have a different meaning of competent and reliable scientific evidence for different interventions); Laine Tr. 56:7-12; *see also* Laine Tr. 229:14-21 (asserting that his study design is "the standard way to do clinical research," regardless of "[w]hether it is GI or some other field" and "[w]hether it is dietary supplements or drugs"). The government's suggestion that its position applies only to Bayer's claims (which are ubiquitous in the industry) is contradicted by Dr. Laine's testimony. Dr. Laine's standard is a *one-size-fits-all* test, which is irreconcilable with the "flexible" standard in the agency guidance and the underlying statute.

II. EVEN IF DRUG-LEVEL RCTS WERE REQUIRED, THIS NOVEL TEST CANNOT BE THE BASIS OF CONTEMPT.

Even if this new test were valid, it cannot be the basis of a contempt motion, because it was not clear and unambiguous. The government had never previously asserted that Drug-Level RCTs were required for any probiotic, or for that matter, any ordinary structure-function claim. As Bayer explained in its opening brief, RCTs were previously required for *disease* claims and some weight-loss claims, but *never* for claims

like the ones Bayer makes. Dkt. No 74 at 36-37. Bayer also explained that, even when RCTs were required, Drug-Level RCTs were not. *Id.* at 37-38.

The government has no response except to say that the "competent and reliable scientific evidence" standard has existed for many years and that the standard is "flexible." But the history of this flexible standard only confirms that the government's position here is entirely novel. Never before has the government required Drug-Level RCTs under this standard. The government has filed five briefs and still has not given a single example.

Further confirming the novelty of this test, no one in the industry possesses a Drug-Level RCT, even though Bayer's claims are ubiquitous in the industry. Merenstein Dec. at 11; *see, e.g.,* Laine Tr. 293:2-293:4. The government's only response is to say that Bayer's manufacturer, Wakunaga, does not make these claims, but this assertion is wrong; indeed, it is disingenuous. [redacted] The government chose to ignore this inconvenient fact.

Finally, the government asserts that Bayer "expected" its novel Drug-Level RCT test. [redacted] But the government fails to mention that the Swiss scientist wanted RCTs to meet *European* approval standards, not U.S. standards. Gisela Latta Affidavit at 1-2 (Duffy Reply Cert. Ex. D). The European Food Safety Authority does not apply the competent and reliable scientific evidence standard, but

instead, applies a drug-like standard. *Id.* Under this extremely high standard, the European agency has not approved *any* probiotic claim.[6]

The government also cites emails and another document showing that Bayer wanted to conduct a clinical trial on IBS, a *disease* state. Dkt. No. 81 at 12-16. There are certainly advantages in clinically proving that a product fights a disease. But by no means were the authors of these documents suggesting that the IBS trial, or any other clinical trial, was legally required to substantiate Bayer's *structure-function* claims. Further, it simply cannot be the case that when Bayer, or another company, wishes to conduct additional research that it raises the legal requirements for supplements.

III. THE GOVERNMENT'S NEW ARGUMENT THAT BAYER DID NOT CITE ANY EVIDENCE SUPPORTING PCH IS MERITLESS.

Because the government's contempt motion is meritless, the government raises a brand new issue. According to the government, Bayer did not "make a single mention of the evidence it purports to have possessed and relied upon since 2008 to substantiate the specific claims at issue." Dkt. No 81 at 18. This is remarkable.

Bayer argued in its very first brief that it possessed "animal and in vitro studies" as well as "numerous randomized clinical trials on the very species of bacteria in PCH." Dkt. No. 23 at 6-7, 9. In its reply, the government did not disagree. Its only response was that none of these trials were "RCT[s] in the appropriate populations

6 [redacted]

using the three-strain formula." Dkt. No. 38 at 11-12. The government contested only the legal sufficiency, not the existence, of such evidence.

Until now, there has been no question that Bayer possessed and relied on numerous public studies and other scientific evidence. In fact, during the government's investigation, Bayer produced almost 100 human studies, in addition to animal and *in vitro* studies. Bayer also produced an internal memorandum from 2006, two years before the product launch, reporting that Bayer scientists conducted a comprehensive "literature review," which returned an "abundant number of matches." Dkt. No. 81 Tab C Exh. 7 at 3. Bayer enumerated over a dozen human studies and two dozen textbooks in this memo, all of which Bayer scientists had reviewed. *Id.* at 4-9. Since 2006, Bayer has "regularly" reviewed the published scientific evidence, which further supports Bayer's claims. *See* Bayer's Response to Interrogatory No. 2 (Duffy Reply Cert. Ex. J) (explaining that "[t]he medical team reviews the scientific support for a product" and through a variety of means it constantly "monitors new research and scientific literature that may affect Bayer products.").

Moreover, Bayer's experts have independently reviewed the science that existed at the time of the product launch and the science that exists today. The experts concluded that Bayer had, and still has, competent and reliable scientific evidence supporting its claims. As Dr. Fennerty determined: "I can state with scientific certainty that in 2008 at the time the product began, there was competent and reliable

scientific evidence to support Bayer's claims for digestive health and the listed occasional symptoms." Supp. Fennerty Dec. at 2; *see* Supp. Merenstein Dec. at 6.

The government asserts that "'digestive health' is not the specific claim at issue," Dkt. No. 81 at 4, but as Bayer's experts explain, competent and reliable scientific evidence supports *both* Bayer's claim regarding "digestive health" *and* its specific claims about constipation, diarrhea, and gas and bloating. *See* Fennerty Dec. at 4 ("Bayer's claims that PCH helps with constipation, diarrhea, gas and bloating [are] accurate and supported by competent and reliable scientific evidence."); Merenstein Dec. at 16 ("[T]here is sufficient scientific data to show that PCH helps with occasional constipation, diarrhea, gas and bloating"). Further, the government is drawing a false distinction between digestive health and symptoms related to digestive health. Supp. Fennerty Dec. at 5-6; Supp. Merenstein Dec. at 2-3. The government's own expert recognized that the term "digestive health" "refer[s] in part to the symptoms at issue in the case." Bushman Tr. 13:4-8. (The deponent later changed his mind and testified he did not know what "digestive health" meant, even though he had used that term in his report). And the government itself has used the term to refer to these precise symptoms. *See* Davis Tr. 219:9-220:8 (Duffy Reply Cert. Ex. G); *see also* AGA Patient Center (Duffy Reply Cert. Ex. H)(describing "good digestive health" by referencing absence of "digestive symptoms such as heartburn, rumbling, nausea, bloating, excessive flatulence, constipation, diarrhea, or abdominal pain and discomfort.").

The government next asserts that Bayer made "implied claims" that "PCH prevents, cures, and treats constipation, diarrhea, and gas and bloating no matter the frequency, and no matter if those symptoms are already present." Dkt. No. 81 at 5. But Bayer never made these "implied claims," and the government cites nothing to support its bald assertion. Government counsel cannot just make up "implied claims" in litigation, contend they are false, and then seek contempt sanctions based on those fictional claims. In any event, the government does not assert that these fictional "implied" claims are disease claims, requiring a Drug-Level RCT.

Finally, the government and Dr. Laine contradict themselves yet again. In his initial declaration, [redacted] Laine Dec. at 20. He likewise questioned the relevancy of [redacted] Laine Dec. at 21. In his supplemental declaration, however, Dr. Laine reverses himself entirely. [redacted]. He cannot have it both ways.

In any event, his assertions regarding those studies are wrong. [redacted]

[redacted]

The government's own expert and FTC representative both agreed in their depositions. [redacted]

CONCLUSION

When the government (1) invents a new legal standard for purposes of litigation, (2) switches its justification for that standard five months into the litigation, and (3) targets a single company that makes product claims that are ubiquitous in the industry, the government has failed to meet an expectation of reasonableness. The Court should reject the government's misguided attempt to hold Bayer in contempt.

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